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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,401	01/11/2006	Yi Yan Yang	6565-73089-01	1799

24197 7590 05/27/2009

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EXAMINER	
GULLEDGE, BRIAN M	

ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
05/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,401	YANG ET AL.	
	Examiner	Art Unit	
	Brian Gulledge	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *21-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/11/06; 8/18/06; 3/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-20) in the reply filed on March 23, 2009 is acknowledged. The traversal is on the ground(s) that the process disclosed by Tang et al. (US Patent 5,296,627) does not anticipate the process recited in instant claim 1 because the material prepared is not a polymer, the monomers are not capable of forming thermosensitvie polymers, and the microemulsion limitation is not disclosed. These arguments are not found persuasive. The material prepared by Tang et al. is a polymer (a latex), and the form of a latex is not excluded by the claims. The Applicant also argues that the monomers used by Tang et al. do not lead to a thermosensitive polymer. There is no support for this assertion, nor does the specification provide a definition for the term, and as ethyl acrylate is sensitive to temperature (it has a glass transition temperature of –24 °C), the process disclosed by Tang et al. meets this limitation. Finally, Applicant argues that the particles of the emulsion disclosed by Tang et al. do not meet the range disclosed in the specification. While Tang et al. does not disclose the average size of the particles in the disclosed process, the range in the specification does not limit the claim, as it is not a definition but rather just one possibility encompassed by the term. Claims 21-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 8 is objected to because of the following informalities: the claim recites the acronym "EGDMA" without spelling it out at least once when used in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "monomer that is capable of forming a thermosensitive polymer" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See *Univ. of Rochester v. G.D. Searle*, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See *Univ. of Calf. V. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. *If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus*. See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any *combination of such identifying characteristics that distinguish the claimed invention from other materials* and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful monomers that are capable of forming a thermosensitive polymer generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions.

Specifically, the specification discloses only a limited number of species of acrylamides and acrylates (paragraph [37]), and these are not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "polymerizable surfactant" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See *Univ. of Rochester v. G.D. Searle*, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See *Univ. of Calf. V. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. *If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus.* See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any *combination of such identifying characteristics that distinguish the claimed invention from other materials* and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful polymerizable surfactants generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions that can polymerize by a variety of mechanisms and thus have diverse structures. Specifically, the specification discloses only a two species of surfactants(paragraph [38]), and these are not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of

identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as acrylamide "derivative" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See *Univ. of Rochester v. G.D. Searle*, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See *Univ. of Calf. V. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. *If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus.* See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any *combination of such identifying characteristics that distinguish the claimed invention from other materials* and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful derivatives of acrylamide "derivatives" generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. The specification discloses no species and thus does not disclose a reasonably representative number of members of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "derivative" is indefinite because it is unclear how far one can deviate from the parent compound without the "derivative" being so far removed therefrom as to be a completely different compound. See the related rejection in the "Written description" section *supra*.

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites that the surfactant is "fluronic68-diacrylate". The specification describes the production of fluronic68-diacrylate from "fluoric-68". Neither the term fluronic68-diacrylate nor the term fluoric-68 is further defined in the specification, ad these terms are not defined in the art. As such, it is unclear what is claimed in the recited process.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al. (*Polymer*, 1997, 38(21), pages 5339-5345) in view of Vakkalanka et al. (*Polymer Bulletin*, 1996, *36*, pages 221-225). Gan et al. discloses the formation of microstructured materials with

pore sizes in the nanometer range using the polymerizable surfactant ω-methoxy poly(ethylene oxide)$_{40}$ undecyl-α-methacrylate, in microemulsions containing methyl methacrylate and 2-hydroxyethyl methacrylate (page 5339, third paragraph) as well as water and the cross-linker ethylene glycol dimethacrylate (page 5342, second full paragraph). Gan et al. further discloses the inclusion of the photo-initiator 2,2-dimethoxy-2-phenylacetophenone in the microemulsions (page 5341, table 1). The microemulsion was placed in a photochemical reactor chamber to polymerize (last paragraph starting on page 5340). Gan et al. does not teach the further inclusion of *N*-isopropylacrylamide.

Vakkalanka et al. teaches the preparation of hydrogels from the polymerization of acrylic acid, 2-hydroxyethyl methacrylate and *N*-isopropylacrylamide (page 221, first paragraph). *N*-isopropylacrylamide is a monomer that forms a thermosensitive polymer according to the applicant's definition (paragraph [29], lines 5-7). Vakkalanka et al. further teaches that due to the inclusion of the *N*-isopropylacrylamide, the material prepared has significant temperature sensitivity (page 221, first paragraph). By including this material, the polymer can react to external stimuli such as physiological changes, which are useful for the delivery of drugs from the material (page 221, second paragraph).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have incorporated *N*-isopropylacrylamide into the polymeric material taught by Gan et al., in order to allow the material to have increased response to changes in temperature, a desirable property with regards to controlled drug delivery. Thus, the taught process of making the material discloses all of the limitations of instant claims 1-13.

Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al. (*Polymer*, 1997, 38(21), pages 5339-5345) and Vakkalanka et al. (*Polymer Bulletin*, 1996, *36*, pages 221-225) as applied to claim 13 above, and further in view of Liu et al. (*Langmuir*, 1997, 13(24), pages 6421-6426). Gan et al. in view of Vakkalanka et al. teach all of the limitations of instant claims 14-20 (see the above rejection) except for the instantly recited amounts of each of the ingredients. Gan et al. teaches using from 10 to 21.25 wt% of the methyl methacrylic acid, from 10 to 21.25 wt% of the 2-hydroxyethyl methacrylate, from 20 to 42.5 wt% of the ω-methoxy poly(ethylene oxide)$_{40}$ undecyl-α-methacrylate, 4 wt% of the ethylene glycol dimethacrylate, and from 15 to 60 wt% of the aqueous component (page 5341, table 1). These ranges overlap some of the instantly recited amounts, and in cases involving overlapping ranges, the courts have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness. *In re Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). However, the relative amounts instantly recited differ, and not all of the instantly recited values overlap these ranges.

Liu et al. teach transparent nanostructure polymeric materials produced from microemulsions containing ω-methoxy poly(ethylene oxide)$_{40}$ undecyl-α-methacrylate, methyl methacrylate, 2-hydroxyethyl methacrylate, water, and ethylene glycol dimethylacrylate (abstract, lines 1-5). Liu et al. teaches that the pore size of this material can be regulated by varying the ratios of the 2-hydroxyethyl methacrylate, ω-methoxy poly(ethylene oxide)$_{40}$ undecyl-α-methacrylate, and water (page 6426, second full paragraph). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have optimized the amounts of these ingredients, as taught by Liu et al., in order to control the

pore size of the polymeric material, which would influence the permeability of the polymeric material to different materials.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gulledge whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMG

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612